

## REMARKS/ARGUMENTS

### **General Remarks**

Claims 1-18 are pending. Claims 1 and 4 are currently amended. Claims 5-18 are added. Claim 1 finds support in the specification: pg 10, Table 1, "Hydrogenated soybean phospholipid" row. Claim 4 has been amended to remove the improper multiple dependency. Claims 5 and 6 find support in the specification: pg 3, lines 19-21. Claim 7 finds support in the specification: pg 3, lines 15-18. Claims 8 and 9 find support in the specification: pg 3, lines 22-24. Claims 10 and 11 find support in the specification: pg 3, lines 25-27. Claim 12 finds support in the specification: pg 3, line 28, to pg 4, line 3. Claim 13 finds support in the specification: pg 5, lines 19-24. Claim 14 finds support in the specification: pg 5, line 27, to pg 6, line 3. Claim 15 finds support in the specification: pg 6, lines 4-14. Claim 16 finds support in the specification: pg 6, lines 15-17. Claim 17 finds support in the specification: pg 10, Table 1, Examples 1-4. Claim 18 finds support in original claim 4. No new matter has been entered.

### **Specification Objections**

The title of the invention has been amended to that suggested by Examiner Karol (Office Action, pg 2, para 3).

The abstract of the disclosure has been amended for grammatical reasons and to be no more than one paragraph and within the range of 50 to 150 words.

Several paragraphs of the specification have been amended to insert "®" after trademarked compounds and to capitalize each letter of the mark as suggested by M.P.E.P. 608.01(v).

Applicants do not believe that the current specification is "in such faulty English that a new specification is necessary" (M.P.E.P. 608.01(q)) and accordingly, have not provided a

substitute specification. If the Examiner can point to specific instances of faulty English, Applicants will be more than happy to further amend the specification.

For the reasons discussed above, Applicants respectfully request the withdrawal of objections to the specification.

### **Claim Objections**

Claim 4 has been amended to remove the improper multiple dependency. Therefore, Applicants respectfully request withdrawal of the objection to claim 4.

### **Double Patenting**

Regarding the double patenting rejections, a terminal disclaimer can be filed, if the claims in the present application remain obvious in view of the claims of *Inagi* (US 5,618,799) at the time of allowance of the present application. Furthermore, additional amendments (if needed for allowance of these claims) may eliminate the double-patenting rejection, making the filing of a Terminal Disclaimer at this time premature. Indeed, M.P.E.P. § 804.02 IV states that, prior to issuance, it is necessary to disclaim each one of the double patenting references applied. Hence, Applicants respectfully request that the examiner contact the undersigned should the present amendments and arguments be accepted and should the present application be otherwise in a condition for allowance. At that time, a terminal disclaimer if warranted can be supplied to expedite issuance of this case.

### **35 U.S.C. § 102(b)**

Claims 1-3 are rejected as anticipated by *Hara*. Applicants submit that *Hara* neither anticipates nor renders obvious the present claims. The Office has asserted that *Hara* discloses “an emulsifier such as hydrogenated lecithin [which] may be present in amounts less than 40% by weight” (Office Action, pg 7, 2<sup>nd</sup> para). However, Claim 1 as amended, requires only 0.3 to 5% by weight of phospholipids. Applicants point out that M.P.E.P. 2131.03(II) states:

“In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, and the reference teaches a broad range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims.”

The M.P.E.P. continues with a reference to *Atofina v. Great Lakes Chem. Corp*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006), stating that “the court held that a reference temperature range of 100-500 degrees C did not describe the claimed range of 330-450 degrees C with sufficient specificity to be anticipatory”. In the case of *Atofina*, the claimed range was 30% of the reference’s disclosure. Applicants’ range of 0.3-5% is only 11.75% of *Hara*’s disclosure, and *Hara* does not disclose any smaller preferred percentage of emulsifiers (i.e. phospholipids). Accordingly, just as in the *Atofina* case, Applicants’ range should be considered as not anticipated by *Hara*.

Applicants also submit that *Hara* does not render obvious Applicants’ claims. *Hara* teaches 0-40% of phospholipid, while Applicants claim 0.3-5%. Moreover, M.P.E.P. 2144.05(III) states:

“Applicants can rebut a prima facie case of obviousness based on overlapping ranges by showing the criticality of the claimed range. ‘The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims.’ ...”

Accordingly, Applicants point out that Comparative Product 1 of Table 1 of the present specification contains 0% of both hydrogenated soybean phospholipid and soybean lecithin which is both outside the range of Applicants and inside the range disclosed by *Hara*. Furthermore, Table 1 shows that Comparative Product 1 has inferior consistency, stirring aptitude and extensibility. Thus, it would not have been obvious to one skilled in the art to

modify *Hara*'s range to be the critical range as claimed by Applicants. Accordingly, *Hara* does not render obvious the phospholipid range of Applicants' claims.

**35 U.S.C. § 103(a)**

Claims 1-3 are rejected as obvious in view of *Komori* and *Ogawa*. Applicants submit that neither *Komori* nor *Ogawa*, nor the combination of the two, renders obvious the present claims. *Komori* discloses some of the elements of Applicants' claim 1, but "does not disclose any embodiments where a phospholipid is present" (Office Action, pg 8, 2<sup>nd</sup> para). The Office relies on *Ogawa* for the assertion that *Ogawa* teaches adding a lecithin compound to reduce viscosity and improve preservation and workability, and it would have been "obvious to one of ordinary skill in the art to add a phospholipid to an aqueous solution as taught by *Ogawa* to ... the wound healing aqueous composition of *Komori*" (Office Action, pg 8, 4<sup>th</sup> para). *Ogawa* teaches "anionic surface active agent[s] as a viscosity depressant" that improve preservability and workability (col. 2, lines 42-47). *Ogawa* lists lecithin as an example of an anionic surface active agent (col. 3, lines 47-63). However, Applicants point out that lecithin is an amphoteric surfactant, not an anionic surface active agent (See *ENCYCLOPEDIA OF CHEMISTRY*, 1989, pg 2223, in which phosphatidylcholine (i.e. lecithin) is defined to possess an amphoteric electrolytic property) (See also: US 6,756,368, col. 8, lines 14-16, "it may be an oily aerosol formulation comprising a nonionic surfactant such as Alacel or Span 80, an amphoteric surfactant such as lecithin or ..."; US 6,509,301, col. 3, lines 50-51, "In a preferred embodiment, the amphoteric surfactant is lecithin ..."; US 6,136,493, col. 13, lines 26-27, "Amphoteric surfactant such as lecithin, natural fats and ..."; US 5,025,004, col. 12, lines 3-5, "In this example, the anionic surfactant (Emphos D70-30C) is replaced with an amphoteric surfactant (lecithin) to prepare ..."; and US 4,323,365, col. 2, lines 66-68, "an illustrative surfactant for this purpose being the water immiscible amphoteric surfactant, lecithin.").

Accordingly, since *Ogawa* teaches that an anionic surfactant reduces viscosity and improves preservation and workability, one skilled in the art would not presume that lecithin, an amphoteric surfactant, would exhibit the same results. Therefore it would not have been obvious to one skilled in the art to add lecithin (i.e. phospholipid) to an aqueous solution as taught by *Ogawa* to ... the wound healing aqueous composition of *Komori* to get reduced viscosity and improved preservation and workability. Accordingly, the combination of *Komori* and *Ogawa* does not render obvious Applicants' claims.

Furthermore, *Ogawa* teaches the monoglyceride of succinic acid as another possible anionic surfactant (col. 3, lines 54-55). Applicants submit the following supplemental experimental data of "D2 Comparative Example".


KW-132 supplemental experiment				
component		present invention example 2	comparative example 1	D2 comparative example
white soft sugar		70.00	←	←
povidone-iodine		3.00	←	←
macrogol 300		1.00	←	←
macrogol 400		10.80	11.30	10.80
conc. Glycerol		1.00	←	←
1,3-butylene glycol		1.00	←	←
propylene glycol		1.00	←	←
hydrogenated soybean phospholipid		0.50		
succinic acid monoglyceride				0.50
poly(oxyethylene) (160)				
poly(oxypropylene) (30) glycol		1.10	←	←
pullulan		0.20	←	←
potassium iodide		0.70	←	←
citric acid		0.10	←	←
sodium hydroxide		0.08	0.0828	0.08
purified water		9.52	9.5172	9.52
consistency (1M : g)	Initial	6.7	59.5	66.0
	R.T.	13.8	127.8	117.2
	40°C	25.5	225.5	320.9
stirring aptitude (1M)	Initial	○	○	○
	R.T.	○	△	△
	40°C	○	×	×
extensibility (1M)	Initial	○	○	○
	R.T.	○	○	○
	40°C	○	△	△

Comparative Example D2 clearly indicates that the addition of succinic acid monoglyceride worsened the consistency, stirring aptitude and extensibility as compared to the already presented Example 2 and even as compared to the already presented Comparative Example 1. Thus, from these results, one skilled in the art would assume that the aqueous solution of *Ogawa* cannot be combined with other art to result in the present invention's superior qualities.

For the reasons discussed above, Applicants submit that all now-pending claims are in condition for allowance. Applicants respectfully request the withdrawal of the rejections, withdrawal of the restriction requirement, and passage of this case to issue.

Respectfully submitted,

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